OCT 1 3 2005

K052755

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

GE Healthcare
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

September 28, 2005

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories

COMMON NAME:

Pulse Oximeter

CLASSIFICATION NAME:

The following Class II classification appears applicable:

Product Code	Classification Name	CFR Section
DQA	Oximeter	870.2700
DPZ	Ear Oximeter	870.2710

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M-NSAT Module (K020479).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5™ E-NSAT module is a single-width plug-in parameter module for a Datex-Ohmeda S 5 modular monitoring system. E-NSAT is used for monitoring arterial oxygen saturation of hospitalized patients.
The Datex-Ohmeda Nellcor Compatible Saturation Module, E-NSAT can be used with the following Datex-Ohmeda modular monitors:

- S/5™ Anesthesia Monitor (AM) with main software S-STD94(A) or S ARK94(A) or newer
- S/5™ Compact Anesthesia Monitor (CAM) with main S-STD94(A) or S ARK94(A) or newer
- S/5™ Critical Care Monitor (CCM) with main software S-ICU97(A) or newer.
- S/5™ Compact Critical Care Monitor (CCCM) with main software S-ICU97(A) or newer.

The E-NSAT module provides continuous non-invasive measurement of the pulse rate and oxygen saturation. Visual and auditory alarms are given for high/low pulse rate and high/low saturation values. The user can adjust the alarm limits.
The E-NSAT module is designed using the Nellcor pulse oximetry technology. The real-time pulse oximetry signal is displayed without any scale. The calculated SpO2 value and pulse rate can be shown in a separate numberfield, or beside the pulse oximetry signal. The parameters can be trended and the trends can be printed with the Recorder module in the monitor or with a separate laser printer.
The accessories are all new for E-NSAT. The accessories are manufactured and tested by Nellcor Puritan Bennet Inc. and distributed by GE Healthcare.

INTENDED USE as required by 807.92(a)(5)

Intended Use:
The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT is intended for use with the Datex-Ohmeda modular multiparameter patient monitors for monitoring arterial oxygen saturation of hospitalized patients.

Indication for use:
The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients. The device is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M NSAT Module (K020479).
The E-NSAT module has the following similarities compared to the predicate M-NSAT (K020479):

- Identical intended use and indications for use
- Use the same operating principle
- The same fundamental scientific technology
- Can be used with the same pulse oximetry -specific monitor software. (Have the same user interface at the monitor)

- The Customer and parameter specifications are the same
- Have the same safety and effectiveness
- Are manufactured using the same processes

The main differences between the new E-NSAT and the predicate M-NSAT (K020479) is primarily due to fact that the new E-NSAT module has the following changes:

- New color, shape, and size and thus differing mechanics
- The front panel and labeling have changed
- The Nellcor OEM Pulse Oximetry electronic measurement board with software, provided by Nellcor Puritan Bennet Inc has changed from MP404 to MP100. The MP100 is an enhanced version of the MP404, and has been previously cleared with the Sandman Express (K040113).
- The Datex-Ohmeda Interface board connecting the measurement board to the monitor have been revised to accommodate the changes to the electronic measurement board
- The E-NSAT connector coding differs to allow use of the accessories specified by Nellcor for the MP100 board
- The accessories (provided by Nellcor) have changed

Based on the analysis and other documentation included in this 510(k) notification and attachments it is evident that the main features and indications for use of the Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT are substantially equivalent to the predicate Datex-Ohmeda M-NSAT Module (K020479).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories has been assessed against the standards below. The device has been thoroughly tested through validation and verification of specifications.

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- FDA/DCRND Reviewer Guidance for Premarket Notification Submissions, November 1993
- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- IEC 60601-1-2:2001 (Electromagnetic compatibility - Requirements and tests)
- IEC 60601-1-4:2000 (Programmable medical systems)
- ISO 9919 (1994) Pulse oximeters for medical use - safety requirements
- EN 865 (1997) Pulse oximeters - Particular requirements
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- FDA/ODE Guidance for Content of Premarket Submission for Software Contained in Medical Devices. (May 11, 2005)

CONCLUSION:

The summary above shows that the Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Datex-Ohmeda M NSAT Module (K020479).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 3 2005

Mr. Joel Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K052755
Trade/Device Name: Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: September 29, 2005
Received: October 3, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT and accessories.

Indications for use:

The Datex-Ohmeda S/5™ Nellcor Compatible Saturation Module, E-NSAT, and accessories are indicated for monitoring arterial oxygen saturation of hospitalized patients. The device is indicated for use by qualified medical personnel only.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K052755